Repackaged Pharmaceuticals in the California Workers' Compensation System:

From Distribution and Pricing Options to Physician and Retail Dispensing

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Abstract

Objective: The California Workers' Compensation (WC) pharmaceutical pricing system cannot price 60% of National Drug Codes (NDCs) (mostly repackaged pharmaceuticals). This study will estimate the lost savings due to repackaged pharmaceuticals and potential cost savings associated with alternative pricing systems for un-priced pharmaceuticals.

Methods: All pain-related repackaged pharmaceuticals were identified by NDC using claims data from the California Workers' Compensation Institute (CWCI) database during 2002.

Results: Repackaged pharmaceuticals represented 55% of all NDCs and 92% of all Medi-Cal non-equivalent NDCs, but only 22% (\$8,494,297/\$38,968,233) of total pharmacy costs.

Total repackaged pharmaceutical costs could be reduced by 36% (\$3,059,177) using an alternative formula based on Medi-Cal. Compared with Medi-Cal priced manufacturer-packaged pharmaceuticals, repackaged pharmaceuticals are approximately 85% more expensive on a cost-per-pill basis.

Conclusion: We propose limiting the generous pricing of repackaged pharmaceuticals. However, Medi-Cal payment rates may be extreme, and more moderate repricing might compensate physician dispensing time more fairly and preserve patient access.

Key Words

Workers' Compensation, Repackaged Pharmaceuticals, Pain Medications, Physician Dispensing, Drug Distribution

Introduction

Problem/Significance

The revised California Workers' Compensation (WC) drug pricing system that went into effect on January 1, 2004 along with other cost cutting reforms tied payments to the much lower Medi-Cal (California's Medicaid) system in order to save costs to the workers' compensation program [Alarcón, 2003; Wilson et al, 2005]. However, approximately 60% of National Drug Codes (NDCs) in the California Workers' Compensation System (many of which were repackaged pharmaceuticals) lacked an equivalent Medi-Cal NDC, necessitating a revision to the old pricing for these NDCs [California Code of Regulations (CCR) 9789.40, 2005].

Proposed Senate Bill (SB) 292 (February 2005) attempted to resolve some of the inconsistencies between the old California Workers' Compensation Fee Schedule and the recently adopted Medi-Cal based reimbursement system, by proposing a new reimbursement scheme for those pharmaceuticals not priced under the Medi-Cal system most of which are repackaged pharmaceuticals [Speier, 2005]. The proposed bill was not approved, but the Division of Workers' Compensation has begun to revise the language of an existing regulation, California Code of Regulations (CCR) title 8 Section 9789.40, which was based on the now approved Senate Bill (SB) 228 that ultimately changed the Official Pharmaceutical Fee Schedule to 100% of the Medi-Cal fee [Alarcón, 2003]. The proposed change (as of 09/06) is pending final approval by the Division of Workers' Compensation, but is to be enacted by 12/06. The revision proposes pricing any NDCs not in the Medi-Cal database with a Medi-Cal equivalent rate of 17% less than the Average Wholesale Price (AWP) plus a dispensing fee of \$7.25 [CCR Proposed Version 9789.40, September, 2006].

Although pharmacies, hospitals, and others can dispense repackaged pharmaceuticals; it is most often the physician who is dispensing repackaged pharmaceuticals in workers' compensation. Although Medi-Cal doesn't cover physician dispensed pharmaceuticals, in the California Workers' Compensation system, the dispensing of pharmaceuticals is unrestricted by formulary or point of service (physician's office, specialty clinic, hospital or pharmacy) and other regulations specifically California Labor Code section 5307.1 and California Code of Regulation Title 8 section 9789.11 state that physician dispensing is a covered service [CCR 9789.11, 2005; California Labor Code 5307.1, 2005; Business and Professions Code 4024, 2005]. Nationwide, about 7% of physicians dispense repackaged pharmaceuticals from their office, which may act to reduce non-compliance in a population where 20% of patients failed to get a prescription filled and 30% of patients don't obtain refills [Reece, 2005; Task Force for Compliance, 1994; American Association of Retired Persons, 1992]. Currently however, there is little information on the value of repackaged pharmaceuticals and if this value is worth the added price. In addition there is minimal information on the effect of repackaged pharmaceuticals on workers' compensation saving and on access to physicians and physician dispensing [Wynn, 2005]. It is important to understand what a repackager and repackaged pharmaceuticals are as well as their pricing, payment and distribution of repackaged pharmaceuticals in order to inform legislation to fairly price repackaged pharmaceuticals without affecting patient access.

Background: Definitions

A "repackaged pharmaceutical" can be defined as a pharmaceutical product that is removed from the original manufacturer container with an original NDC and put into a new

container with new quantities, therefore requiring a new NDC, with a new repackaging company label and price for the medication.

A "pharmaceutical repackager" can be defined as a company that specializes in selling their own NDC designated products, which are referred to as repackaged pharmaceuticals. Although a company must retain a manufacturer license to repackage pharmaceuticals many of these companies specialize in other areas of the pharmaceutical distribution chain and would rarely be referred to as a manufacturer. Companies that repackage pharmaceuticals can be referred to as pharmaceutical repackagers, but also as wholesalers, and retailers. Figure I provides a look at the drug distribution system including the flow of repackaged pharmaceuticals and the subsequent price changes that follow a drug from the manufacturer to the retailer and ultimately to the patient.

Background: Drug Distribution

Of the \$172 billion worth of prescription drugs sales that American pharmaceutical manufacturers produced and shipped in the year 2001, 46% were shipped directly from the manufacturer to retailers such as pharmacies, clinics, or prescribing doctors as well as to institutional pharmacies, closed-door pharmacies, and foreign markets with a manufacturer NDC and label [Lee, 2005].

The remaining 54% of production sales go through the primary and secondary wholesale market and then to the retailer and include wholesalers, retailers and pharmaceutical repackager only companies [Lee, 2005]. In the U.S., the primary wholesale market is dominated by three major wholesalers that account for 90% of the market ("The Big Three"). They are Cardinal Health, Inc. of Ohio, McKesson Corp. of California, and AmerisourceBergen of Pennsylvania [Department of Health and Human Services, 2005].

Roughly 12-15 smaller regional wholesale distributors (secondary wholesalers) represent the remaining 10% of the wholesaler market and primarily repackage pharmaceuticals. The largest repackaging only companies are Allscripts, Physician Total Care, and Southwood Pharmaceuticals [Lee, 2005; Department of Health and Human Services, 2005].

The current workers' compensation drug pricing system creates a potential incentive to increase drug reimbursement through the use of repackaged pharmaceuticals. The extent and reasons for use of repackaged pharmaceuticals in workers' compensation are currently unknown and are the motivating factor for the present study.

Objective

The purpose of this paper is to assess the cost and utilization of repackaged pharmaceuticals in a selected sample of California Workers' Compensation pharmacy claims and to estimate lost savings due to repackaged pharmaceuticals and potential savings of alternative pricing strategies for repackaged pharmaceuticals in workers' compensation.

In addition, we will explain repackaged pharmaceutical distribution and assess the relationship between available predictor variables and repackaged pharmaceutical utilization to determine what characteristics explain costs to identify reasons for repackaged pharmaceutical use.

Methods

To determine how repackaged pharmaceuticals affect drug pricing we compared Medi-Cal reimbursement rates for pricing workers' compensation claims in California for the year 2002, prior to the new drug legislation with those of the old fee schedule pricing.

Sample

We used a sample of workers' compensation prescription claims collected from the California Workers' Compensation Institute (CWCI), a private, nonprofit organization of workers' compensation insurers who collect claims from their members into the Industry Claims Information System (ICIS) Dataset.

For this study we selected only pain and pain related medications that were identified from a previous study, which comprise an estimated 38.9% of the total CWCI member prescription claims and 52.5% of the total CWCI workers' compensation pharmacy payments in 2002 [Wilson et al, 2005] (Table I). The CWCI dataset also includes the billed amount, paid amount, drug NDC and name dispensed.

Identification of Repackaged Pharmaceuticals

Licensing designations that are required at the state and federal level for a company to repackage pharmaceuticals and regulatory guidelines including the Code of Federal Regulations (CFR) Parts 205, 207 and 211 were used to determine which companies can be referred to as a pharmaceutical repackager.¹

In addition to using licensing methods to identify pharmaceutical repackagers three drug information references including the Drug Topics Red Book (only since 2003), First

production and sale of a specific pharmaceutical [Code of Federal Regulations (CFR) Title 21 Part 207, 2005; CFR Title 21 Part 211, 2005].

¹ Currently, the only valid method of identifying a repackaged pharmaceutical is from the NDC and accompanying application material provided to the FDA. The first set of numbers' represents the labeler code, a number that is provided by the FDA to the listing firm, and is specific to the firm manufacturing or repackaging the medication. The second (product/drug code) and third (quantity/package code) sets of numbers are designated by the listing firm [CDER National Drug Code Directory, 2005]. However, no specific coding in an NDC allows an interested party to determine whether the origin of the product is a manufacturer or company that is simply repackaging the pharmaceutical only. The FDA, the company itself, or a drug information reference such as Red Book could be contacted or referenced to obtain such information. Additional information detailed in the FDA application (Form 2656, Form 2657) for registering and submitting a NDC drug listing requires the listing firm to disclose information pertaining to the origin of the medication identifying whether the pharmaceutical is repackaged or is manufactured through a particular company [CDER Guidance for Industry Forms, 2005]. To repackage a pharmaceutical, a company at a minimum must be licensed as a manufacturer. To comply and conduct business as a manufacturer, certain guidelines, specifically the Code of Federal Regulations Title 21 Part 207 and 211 must be followed. Part 207 describes the registration process for submitting a drug that is to be manufactured. A manufacturer license in addition to allowing drug manufacturing also provides a company the ability to label and package the pharmaceutical into containers making a manufacturer a pharmaceutical packager. Part 211 outlines current good manufacturing practices (cGMPs) for finished pharmaceuticals, which manufacturers must follow in order to continue

DataBank and Medi-Span were accessed to identify repackaged pharmaceuticals [First DataBank NDDF 2005; Medi-Span 2005; Red Book, 2005].

Assigned Cost per Claim

We used actual published Medi-Cal pharmacy payments, specifically the amount paid out by the Medi-Cal system for 2002 collected from the Medi-Cal Drug Utilization Database where an equivalent NDC existed. On January 1, 2004 the California Legislature approved a new formula based on Medi-Cal reimbursement rates that calculates the California Workers' Compensation pharmacy rates using the lower amount of the Estimated Acquisition Cost (EAC) which is approximately the Average Wholesale Price (AWP)-17%, or the Federal Allowable Costs (FAL) or the Maximum Allowable Ingredient Cost (MAIC), or the Usual and Customary Price as well as a dispensing fee of \$7.25 [Medi-Cal Pharmacy Manual, 2005]. For repackaged pharmacy claims, where there would be no equivalent NDC, a straight fee schedule based on the Average Estimated Acquisition Cost (AWP-17%) plus a dispensing fee of \$7.25 will be utilized. In addition, we used alternative formulas including: 1) AWP-10% + \$8.75 and 2) AWP-10% + \$7.25 for additional cost comparisons between the current and proposed new pricing systems to inform potential new legislation.

Cost Comparisons

A total of 1,315 workers' compensation NDCs and their total costs provided the drug sample for comparison between the former California workers' compensation fee schedule and the newly adopted Medi-Cal fee schedule. We used the amount paid, the total number of prescriptions and the assumption that payments were based on the 2002 California Workers' Compensation pharmaceutical fee schedule to create a formula to calculate the average number of pills per prescription. The selected 2002 workers' compensation pharmacy costs

for each NDC are repriced using Medi-Cal prices paid in 2002 per pill for the same NDC to determine any potential changes in costs. The differences in total annual workers' compensation cost between the old and new pharmacy fee schedules by drug name, by therapeutic class, for all brand or, all generics, and for all the selected drugs together were assessed in a previous article [Wilson, 2005]. The focus of this analysis is on repackaged pharmaceuticals with some reference and comparison to manufacturer packaged pharmaceutical utilization and costs.

Analysis: Univariate Analyses

We used both univariate and multivariate analyses. We determined descriptive information on the mean costs, utilization, and characteristics of repackaged pharmaceuticals for pain and pain related medications in the California Workers' Compensation System.

The cost differences of repackaged pharmaceuticals priced with the pre-2004 pharmacy fee schedule are compared to the most recently adopted Medi-Cal fee schedule using the Average Estimated Acquisition Cost reimbursement rate of AWP-17% + \$7.25 and two other possible pricing systems. The difference in costs savings between the two systems are tested using independent t-tests across the most commonly designated therapeutic classes for pain and pain-related medications due to wide variations and potential indications of the selected pain and pain related medications.

An additional cost per pill analysis was performed to determine any cost differences between manufacturer packaged pharmaceuticals and repackaged pharmaceuticals by individual medication and for all brand, brand only or all generic medications due to varying utilization rates and cost differences that occur as a result of patent and licensing restrictions. The cost per pill analysis also assessed cost differences across the pre 2004, current and

newly proposed pharmacy fee schedules, realizing that cost/pill comparisons don't reflect cost per daily dose. Although cost/pill still doesn't account for daily patient dose, it can give a fair comparative assessment across these pricing options by accounting for some of the differences in quantity prescribed.

Analysis: Multivariate Analyses

Using SAS statistical software, regression analyses were performed to determine any relationship between predictor variables and the utilization and costs of repackaged pharmaceuticals. Predictor variables affecting the average cost per pill (adjusts for the quantity prescribed) of repackaged medications were assessed using two models including a logarithmic (log) Ordinary Least Square Regression (Proc Reg) with dummy variables and Generalized Linear Model (Proc GenMod) with categorical variables (SAS version 8.2) to allow for a robust analysis.

Five categorical variables which included all selected pain and pain related therapeutic drug classes (7 categories), sub categories including brand with generic equivalent, generic, and brand only medications (3 categories), time on market including less than 7 years, 7 to 15 years, and greater than 15 yrs (3 categories) and the presence of a Federal Allowable Limit price (2 categories) were modeled as dummy variables or categorical variables depending on the regression method. The total average cost per pill was not normally distributed across NDCs so the OLS regression modeled the total log cost per pill as the dependent variable and this log cost was normally distributed while the Generalized Linear Modeled the actual cost per pill.

Results

Repackaged Pharmaceutical Costs in the California Workers' Compensation System

Pain and pain related repackaged pharmaceuticals represented a total of 55.3% (727 NDCs) of all the selected pain and pain related California Workers' Compensation NDCs (1,315 NDCs), but only 21.8% (\$8,494,297) of total pain and pain-related costs (\$38,968,233) and 27.8% (128,148) of the prescriptions in our dataset (Table I). Generic medications accounted for the majority of repackaged costs (88%). When generics are available very few branded medication costs are from repackaged pharmaceuticals, and only 11% of the brand only medication costs are from repackaged pharmaceuticals. When looking at individual repackaged medications, generic versions of hydrocodone, naproxen and carisoprodol, with generic repackaged pharmaceutical costs ranging from \$999,080 to \$2,677,870, contributed the highest costs of all pain and pain related repackaged pharmaceuticals in our California Workers' Compensation CWCI dataset (Table I).

The medications with the greatest proportion of their total WC medication costs attributed to repackaged pharmaceuticals include gabapentin, a brand only medication (100%) and generic propoxyphene (98.1%). But gabapentin accounted for only 0.3% (\$23,414/\$8,494,298) of total workers' compensation repackaged pharmaceutical costs and only 0.06% (\$23,414/\$38,968,233) of total workers' compensation pain and pain related pharmacy costs. Most repackaged pharmaceuticals only represented on average approximately 18% of total pharmacy costs by medication. Generic naproxen and generic carisoprodol accounted for the largest amount of repackaged pharmaceutical dollars (77.5%) and (70.3%) respectively and combined represent 9.6% of total pain and pain related pharmacy costs.

Skeletal muscle relaxants/anticonvulsants (\$3,258,305) (38.4%) and non-steroidal anti-inflammatory drugs (\$3,434,563) (40.4%) had the largest costs associated with repackage pharmaceuticals by therapeutic class and highest percentage of repackaged pharmaceutical costs (Table II). Non-Steroidal anti-inflammatory drugs (NSAIDS) and schedule III or greater narcotics have repackaged pharmaceutical costs totaling 25.8% (\$3,434,563/\$13,324,931) and 23.6% (\$1,748,605/\$7,395,349) of all pharmacy costs for each therapeutic drug class (Table II). Although repackaged pharmaceutical costs for skeletal muscle relaxants/anticonvulsants and NSAIDS are similar, skeletal muscle relaxants/anticonvulsants are only 52.8% of their total costs while repackaged NSAIDS are 25.8% of their total costs.

Repackaged Pharmaceutical Sources

Companies that supply repackaged pharmaceuticals that had the highest number of NDCs used include Southwood Pharmaceuticals (57.7%), Pharma Pac (23.9%) and Allscripts (4.9%). Utilization based on the total number of prescriptions per company identified the same three sources as highest,, which included Southwood (47.8% of all repackaged pharmaceutical prescriptions), Pharma Pac (37.8% of all repackaged pharmaceutical prescriptions), and Allscripts (7.1% of all repackaged pharmaceutical prescriptions) (Figure II).

When looking at the sources of repackaged pharmaceuticals compared to all workers' compensation pharmacy costs (\$38,968,233), Southwood repackaged pharmaceuticals represented the highest costs (\$4,897,300) followed by Pharma Pac (\$2,693,302) and much lower is Allscripts (\$415,051) (Figure I). Southwood repackaged pharmaceutical costs contributed the largest percentage of all repackaged pharmaceutical costs (33.1% of all

repackaged pharmaceutical costs) followed by Pharma Pac (31.7% of all repackaged pharmaceutical costs) and Allscripts (19% of all repackaged pharmaceutical costs).

Loss of Savings from Repackaged Pharmaceuticals

If all repackaged pharmaceutical NDCs were repriced with the average Estimated Acquisition Cost (AWP-17% + \$7.25) instead of the old WC formula (Brand: AWP+10% + \$4.00; Generic: AWP+40% + \$7.00) currently used, then total repackaged pharmaceutical costs could be significantly reduced by 36%, an additional \$3,059,177 in savings (p<0.0001) (Table II). Non-steroidal anti-inflammatory drugs showed the greatest potential for cost savings for repackaged pharmaceuticals because of large (61.4%) cost reductions (p<0.0003) with average EAC repricing of repackaged pharmaceuticals and the large percentage of repackaged pharmaceuticals costs contributed by NSAIDS (40% of all repackaged pharmaceutical costs). While anti-ulcer agents and anti-anxiety/sleep aids showed slightly lower cost reductions (52% and 48%) respectively, the potential for large repackaged pharmaceutical cost savings to the WC system is limited because of the low percentage of repackaged pharmaceutical costs that are attributed to anti-ulcer agents (0.03% of all repackaged pharmaceutical costs) and anti-anxiety agents/sleep aids (0.26% of all repackaged pharmaceutical costs).

Multivariate Analysis: Predicting Cost

For repackaged pharmaceuticals, the OLS regression analysis predicted an adjusted r-square of 0.092 verifying our predictor variables predicted up to 9.2% of the average total log costs per NDC for repackaged pharmaceuticals. The residuals were normally distributed; therefore it was not necessary to retransform log costs into actual values for interpretation. In addition, by not transforming the log costs into actual values we prevent any retransformation

bias [Manning, 2001; Manning, 1998] (Table IIIa). Variables that were significantly predictive of increasing total average repackaged costs per NDC included generic medications (p=0.005) and time on market < 7yrs (p=0.006). To assure the robustness of the log model regression, we modeled the same predictor variables using the Generalized Linear Model (Proc GenMod in SAS) to predict the actual total average cost per pill with a gamma distribution and a log link function to retransform the log values for interpretation. It was found that predictor variables were the same across regression methods (deviance=89.1; log likelihood = -1597.89). The same regression analyses, both log OLS (r-square of 0.1157) and Generalized Linear Model (Deviance=104.9; Log Likelihood= - 1452.47) were performed for manufacturer packaged pharmaceuticals total average cost per pill (Table IIIb). Again, for the manufacturer packaged pharmaceuticals the predictor variables were the same across regression methods.

Predictor variables across regression methods were similar, but not identical. Using the log OLS regression, we found brand medications with generic equivalents to be significantly predictive of lower manufacturer packaged pharmaceutical costs. No variables were predictive of higher total manufacturer packaged pharmaceutical average costs as compared to repackaged pharmaceuticals. Generic medications were predictive of higher costs for repackaged pharmaceuticals and of lower costs for manufacturer packaged pharmaceuticals confirming that the repackaged pharmaceutical workers' compensation market is largely composed of generic medications, but not necessarily cheaper generic medications.

Average Cost per Pill: Manufacturer and Repackaged Pharmaceutical Comparisons

An analysis of cost/pill of only oral capsules and tablets of the selected pain and pain related medications (1,210 of 1,315 total NDCs) was performed to assess any cost differences between manufacturer packaged and repackaged pharmaceuticals and across alternative proposed options for repackaged pharmaceuticals. Although cost/pill still doesn't account for daily patient dose, it can give a fair comparative assessment across these pricing options (Table IV) by accounting for some of the differences in quantity prescribed. On average, manufacturer packaged prescriptions contained 56 pills/prescription compared to 39.2 pills/prescription for repackaged pharmaceuticals. Overall the cost per pill analysis revealed that prior to the implementation of Medi-Cal pharmacy payment rates, pre 2004 costs per pill for manufacturer and repackaged pharmaceuticals on average were similar (Column (1): \$2.09/pill compared with Column (4): \$2.23/pill) (Refer to columns in Table IV).

However, when manufacturer packaged medications are priced with 2002 Medi-Cal published rates and repackaged pharmaceuticals are priced with the pre 2004 pharmacy fee schedule, repackaged pharmaceuticals (Column (4): \$2.23/pill) over all pain and pain related medications are on average more expensive (85% higher) than manufacturer packaged pharmaceuticals (Column (2): \$1.20/pill) showing the lost savings from non-equivalent NDCs for repackaged pharmaceuticals with the current legislation. Only two medications were less expensive on a cost per pill basis, lansoprazole (Column (4): \$1.66/pill repackaged vs. Column (2): \$4.14/pill manufacturer) and cyclobenzaprine (Column (4): \$1.35/pill repackaged vs. Column (2): \$1.48/pill manufacturer).

We also determined that when we repriced manufacturer and repackaged pharmaceuticals with the current average Medi-Cal rate, which is AWP-17% + \$7.25 (EAC), their cost per pill over all pain and pain related medications is identical (Column (3): \$1.26/pill and Column (5): \$1.26/pill). Finally we compared two other proposed payment rates for repackaged pharmaceuticals, which might be fairer, including AWP-10% + \$7.25 (5.5% greater than the EAC) and AWP-10% + \$8.75 (13.4% greater than the EAC), varying both AWP price and dispensing fees. We found that the overall reductions from the current pricing are between 36% - 40% [\$1.33: (Column 6) and \$1.43 (Column 7) compared to \$2.23: (Column 4)] for both additional proposed rates.

The additional dispensing fee added to the AWP-10% price adds about \$.10/pill, while AWP-17% reduces the cost/pill by \$0.07/pill more from AWP-10% with the same dispensing fee a decrease of 57% from current repackaged pharmaceutical prices. Varying the dispensing fee may allow the dispenser such as a physician to keep more of the payment than if the AWP alone is changed; depending on negotiations made with pharmaceutical repackagers and insurers.

Discussion

From our analysis it seems repackaged pharmaceuticals do not result in the loss of significant cost savings to the California Workers' Compensation System. With over 55% of the NDCs used by the workers' compensation originating from a repackager, only about 21% of the total costs are attributed to repackaged pharmaceuticals. Potential savings when substituting the average EAC as the price for repackaged pharmaceuticals reduced costs by about \$3 million. A previous study estimated potential cost savings of 29.5% (approximately \$11 million) when assessing 2002 Medi-Cal rates for pain and pain related medication NDCs

that were equivalent with the Medi-Cal system [Wilson et al, 2005]. When potential costs savings from our analysis of non-equivalent repackaged pharmaceutical NDCs is added to the cost savings from the new fee schedules assessed by Wilson et al., the California Workers' Compensation System could potentially save up to 36.9% (\$14,368,736), an additional 7.9% savings.

However, the problem remains in workers' compensation that most, if not all repackaged pharmaceuticals can not be priced using a published Medi-Cal rate, which therefore limits the extent of savings that can be brought to the workers' compensation program and may create incentives for more use of repackaged pharmaceuticals to enhance payment. Our study also found that the repackaged pharmaceutical workers' compensation market is largely composed of generic medications, but not necessarily cheaper generic medications, a result similar to that found in study conducted by RAND [Wynn, 2005].

Furthermore, in a recent report by CWCI, it was found that as much as 51.5% of 2004 California Workers' Compensation pharmacy payments were for repackaged pharmaceuticals although the percentage of prescriptions (30.5%) remained equivalent to the results (27.8%) found in this study which may reflect increased payments since our 2002 data [Swedlow, 2005].

Changes in the reimbursement of repackaged pharmaceuticals in the workers' compensation system however has an implication for repackagers, for physician dispensing and for patients who may be inconvenienced if lower prices cause physicians to stop the practice of office dispensing. As workers' compensation legislators consider regulations for pricing repackaged pharmaceuticals the impact on these players must be considered. Physician dispensing may add to the availability of medications, instead of patients traveling

between pharmacies to obtain multi-ingredient prescriptions, especially important for those requiring pain medications such as patients in workers' compensation [Lober et al, 1988]. Physician dispensing of repackaged medications may reduce medication errors from poor handwriting and sound alike medications, and repackaged pharmaceuticals may also provide reduced costs to the workers' compensation system, insurance companies and employer premiums by taking advantage of price discounts available on drug products, reducing overhead costs from low volume transactions, as well as supplying medications with a quick turnaround or providing sales to a remote area, where high volume pharmaceuticals may be unnecessary [Department of Health and Human Services, 2005].

However, others suggest that repackaging pharmaceuticals may act primarily to increase drug prices needlessly and that physician dispensing acts primarily to increase physician profits. From a societal perspective, repackaging pharmaceuticals raises concerns in regards to ethics, conflicts of interest, and patient welfare [Abood, 1989]. In addition the current workers' compensation pharmacy pricing system may be acting as an incentive to increase repackaged pharmaceutical use by other retailers to avoid cost cutting efforts. Our study offers alternative pricing systems to close the 'loophole' in the current legislation while trying to maintain access to physician dispensing.

Limitations

Our study has several limitations that should be noted. First, we used CWCI data, which is a sample of drug use in workers' compensation, not all drug use. Secondly, we selected only pain and pain related drugs, which is not all the drugs in the CWCI database, for our study. This group of drugs, represents a majority of workers' compensation drugs

and are representative of the types of drugs that are used by injured workers, however other drugs may have different patterns of drug costs and savings.

Another limitation is that we used 2002 drug data and some of the drugs that were only available as brands then, now have generics available so savings could differ in future years. For example, eleven of the twenty-three pain related drugs were only sold as brand name products in 2002 with five new medications approved for generic use since that time. In late 2001 omeprazole was released, tramadol and tizanidine were released during the middle of the year in 2002 followed by, paroxetine and gabapentin in 2003, and more recently rofecoxib has been removed from the market due to potential adverse effects [CDER Label and Approval History, 2005].

Not all NDCs that did not have a Medi-Cal equivalent cost are repackaged pharmaceuticals. We found 93 NDCs that were not repackaged pharmaceuticals in our data and these are manufacturer packaged NDCs sold directly by the manufacturer. Their impact on overall costs was minimal (approximately \$500,000) however. These NDCs are not restricted from Medi-Cal coverage and may have only lacked utilization for the selected study quarter or may be limited from utilization due to the use of medical licensing agreements, formularies and prior authorization procedures which allows the utilization of different NDCs than those used by the workers' compensation system. It may be that there will be always some random variation in NDCs which don't match the two systems yet are not repackaged due these factors.

Conclusion

With the costs of pharmaceuticals increasing each year in the California Workers'
Compensation System and repackaged pharmaceuticals continuing to return high

reimbursement rates through legislative 'loopholes', an opportunity to implement cost containment strategies such as changes in draft regulations for SB 228 (revised legislation to California Code of Regulations 9789.40) are recommended to reduce excess resource utilization. However, due to additional costs associated with repackaged pharmaceuticals and the potential compliance and benefit with point of contact service with repackaged pharmaceuticals a more generous dispensing fee to supplement the extra costs associated with physician dispensing practices and their value may be in order. However, if the workers' compensation legislation suggests a fee schedule that is too low, it is possible that physicians using repackaged pharmaceuticals for their workers' compensation patients will stop taking workers' compensation patients or stop providing point of service medications to them. In fact, such fears are outlined in the draft legislation to revise CCR 9789.40 (Draft Version as of 09/06). This could lead to patient access problems to physicians and to patients receiving their medications. In order to provide a fair, but not excessive price in workers' compensation legislation it is necessary to understand how repackaging fits into the WC system and the overall drug distribution system and we describe that through our drug distribution flowchart.

Repackaged pharmaceuticals add to the overall pharmacy costs in the California Workers' Compensation System, but no research has been conducted comparing the cost efficacy of treating patients with repackaged pharmaceuticals compared with pharmacy dispensed medications or assessing the additional value associated with repackaged pharmaceuticals. Future studies should examine if this added price is worth the increased access that repackaged pharmaceuticals afford.

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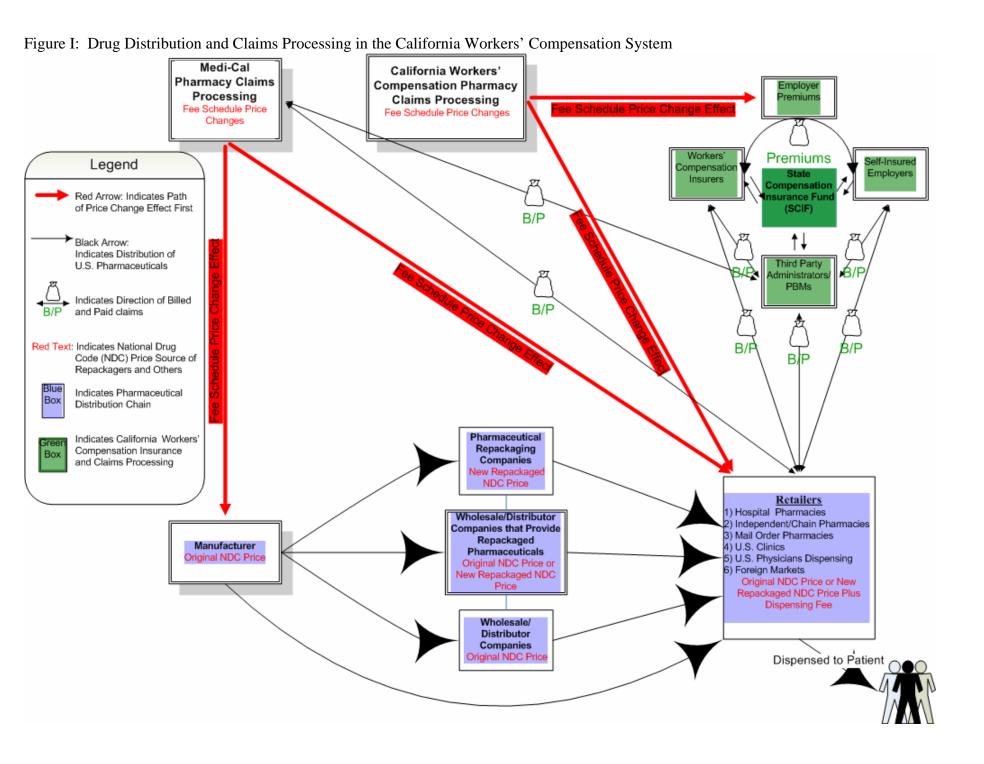


Table I: Repackaged and Manufacturer Packaged Pharmaceutical Use and Costs for Pain and Pain-Related Medications in the California Workers'

Compensation System Using 2002 CWCI Pharmacy Costs¹

	Total Pain and Pain Related Pharmacy Costs (\$)	Pain and Pain Related Manufacturer Packaged Pharmaceutical Costs (\$)	Pain and Pain Related Repackaged Pharmaceutical Costs (\$)	Percentage of Total Pain and Pain Related Pharmacy Costs that are Repackaged	Number of Pain and Pain Related Repackaged Pharmaceutical NDCs	Percentage of Total Pain and Pain Related NDC's that are Repackaged	Number of Pain and Pain Related Repackaged Pharmaceutical Prescriptions	Percentage of Total Pain and Pain Related Prescriptions that are Repackaged
Grand Total	\$38,968,233	\$30,473,935	\$8,494,298	21.80%	727	55.29%	128,148	27.77%
Total Brand/Generic*	\$8,714,227	\$8,638,047	\$76,180	0.87%	120	43.96%	1,501	3.46%
Alprazolam	\$44,425	\$44,425	\$0		0		0	
Carisoprodol	\$403.117	\$402,883	\$234	0.06%	4		6	0.26%
Fentanyl	\$1,529,384	\$1,529,384	\$0		0		0	0.00%
Cyclobenzaprine	\$27.086	\$22.895	\$4.192	15.47%	12	0.00,0	145	16.22%
Fluoxetine	\$540,749	\$537,050	\$3,699	0.68%	10		39	1.30%
Hydrocodone	\$821,488	\$798,447	\$23,041	2.80%	34		490	3.39%
Morphine	\$414,052	\$414,052	\$0		0		0	0.00%
Naproxen	\$18,355	\$14,307	\$4,047	22.05%	18		80	31.01%
Oxycodone	\$4,400,160	\$4,398,101	\$2,059	0.05%	4		14	0.12%
Propoxyphene	\$80,557	\$73,100		9.26%	7		243	11.67%
Relafen	\$434,854	\$403,402	\$31,452	7.23%	31	91.18%	484	9.42%
Total Brand Only	\$16,728,704	\$15,778,703	\$950,001	5.68%	168	69.71%	13,240	8.05%
Celecoxib	\$4,870,023	\$4,387,545	\$482,478	9.91%	28		6,013	13.73%
Gabapentin	\$23,414	\$0	\$23,414	100.00%	21	100.00%	263	100.00%
Lansoprazole	\$398,309	\$398,268		0.01%	1	14.29%	1	0.05%
Metaxalone	\$401,712	\$375,208	\$26,505	6.60%	19		704	10.12%
Omeprazole	\$664,266	\$662,408	\$1,858	0.28%	5		15	0.43%
Paroxetine	\$678,698	\$670,206	\$8,492	1.25%	7		82	1.46%
Rofecoxib	\$4,586,712	\$4,318,037	\$268,674	5.86%	35	67.31%	3,283	7.30%
Sertaline	\$607,856	\$607,856	\$0	0.00%	0		0	0.00%
Tizaidine	\$724,219	\$724,219	\$0	0.00%	0	0.00%	0	0.00%
Tramadol	\$1,902,544	\$1,779,070		6.49%	28	90.32%	2,686	10.48%
Venlafaxine	\$696,863	\$693,507	\$3,356	0.48%	7	35.00%	38	0.80%
Zolpidem	\$1,174,089	\$1,162,379	\$11,710	1.00%	17	80.95%	155	1.07%
Total Generic**	\$13,525,302	\$6,057,185	\$7,468,117	55.22%	439	54.81%	113,407	44.72%
Alprazolam	\$300,045	\$288,268	\$11,777	3.93%	17		238	4.23%
Carisoprodol	\$3,807,100	\$1,129,230	\$2,677,870	70.34%	55	58.59%	20,234	43.64%
Cyclobenzaprine	\$784,490	\$258,399	\$526,091	67.06%	52	75.00%	11,799	61.07%
Fentanyl	\$33,328	\$32,998	\$330	0.99%	2	14.29%	3	0.92%
Fluoxetine	\$80,279	\$70,774	\$9,505	11.84%	4	18.18%	60	11.67%
Hydrocodone	\$3,983,641	\$2,984,561	\$999,080	25.08%	142	54.46%	28,715	23.90%
Morphine	\$477,929	\$477,929	\$0		0		0	0.00%
Naproxen	\$3,413,701	\$766,744	\$2,646,957	77.54%	120	54.01%	36,856	72.45%
Oxycodone	\$36,383	\$36,383	\$0		0		0	0.00%
Propoxyphene	\$607,119	\$11,567	\$595,552	98.09%	40		15,488	98.00%
Relafen	\$1,287	\$332		74.22%	7	77.78%	14	77.78%

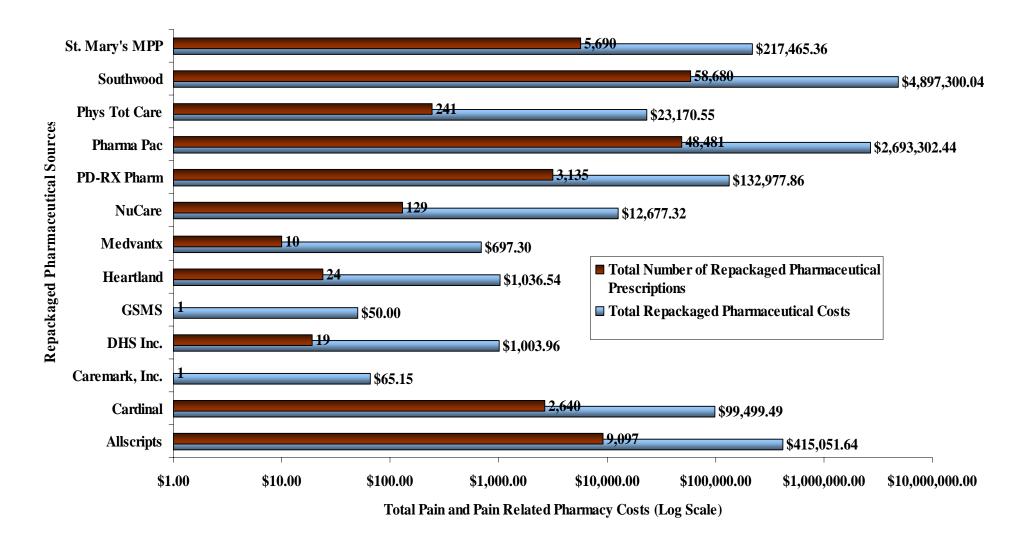
CWCI: California Workers' Compensation Institute; NDC=National Drug code

Drug status prior to 2002 was used for this analysis (generic, brand with generic equivalent, or brand only)

¹ Pre 2004 Pharmacy fee Schedule: Generic drugs: (AWP x 1.4) + \$7.50 dispensing fee, Brand name drugs: (AWP x 1.1) + \$4.00 dispensing fee

^{*} Brand costs for drugs that have both brand and generic equivalents; ** Generic costs for drugs that have both brand and generic equivalents

Figure II. Costs and Utilization of Pain and Pain Related Repackaged Pharmaceuticals in the California Workers' Compensation System for 2002 by Origin of Sale¹



Company Abbreviations: St. Mary MPP: St. Mary's Managed Prescription Program; Southwood: Southwood Pharmaceuticals; Phys Tot Care: Physician's Total Care; PD-RX Pharm: PD-RX Pharmaceuticals; GSMS: Golden State Medical Supply; DHS, Inc.: Dispensing Health Solutions

¹ Pre 2004 Pharmacy fee Schedule: Generic drugs: (AWP x 1.4) + \$7.50 dispensing fee, Brand name drugs: (AWP x 1.1) + \$4.00 dispensing fee

Table II: Total Estimated Costs and Percent Savings Using Alternative Pricing Methods for 2002 Pain and Pain Related Repackaged Pharmaceuticals by

Therapeutic Class

	F 2002 A Brand: 1109 Generic:140	Workers' Compensation Rates: actual Costs %*AWP + \$4.00 %*AWP + \$7.00 Costs = \$38,968,233)	Proposed Rep Manufac 2002 Medi-C Rep AWP-	to Pre October 2004 and ackaged Drug Rates: turer Packaged: Cal Published Costs§ packaged: -17% + \$7.25 y Costs = \$24,599,497)	Percent Change and Significance for Repackaged Pharmaceuticals Between Pre 2004 and Proposed Fee Schedule Costs	
	Manufacturer Packaged	Repackaged *** (Percentage of Total Pharmacy Costs)	Manufacturer Packaged	Repackaged *** (Percentage of Total Pharmacy Costs)	(t-test and p-value)***	
Grand Total	\$30,473,935	\$8,494,298 (21.8%)	\$19,164,376	\$5,435,121 (22.15%)	36.01% (t =4.87; p<0.0001)	
Anti-Axnxiety/Sleep Aids	\$1,495,071	\$22,555 (1.49%)	\$780,269	\$11,800 (1.49%)	47.68% (t=3.08; p=0.004)	
Antidepressants	\$2,579,394	\$25,050 (0.96%)	\$1,587,539	\$17,269 (1.08%)	31.06% (t=2.62; p=0.01)	
Anti-Ulcer Agents	\$1,060,677	\$2,831 (0.27%)	\$693,860	\$1,356 (0.05%)	52.08% (t=1.91; p=0.1)	
Schedule II narcotics	\$6,888,848	\$2,389 (0.03%)	\$4,775,828	\$1,584 (0.03%)	33.7% (t =1.77; p=0.14)	
Schedule III or greater narcotics	\$5,646,744	\$1,748,605 (23.64%)	\$3,404,154	\$1,485,946 (31.13%)	15.02% (t=6.40; p<0.0001)	
NSAIDS	\$9,890,367	\$3,434,563 (25.78%)	\$6,297,786	\$1,327,551(17.02%)	61.35% (t=3.68; p=0.0003)	
Skeletal Muscle Relaxant/Anticonvulsants	\$2,912,834	\$3,258,305 (52.8%)	\$1,624,941	\$2,589,614 (61.44%)	20.52% (t=3.29; p=0.001)	

^{*}Pre 2004 Pharmacy fee Schedule: Generic drugs: (AWP x 1.4) + \$7.50 dispensing fee, Brand name drugs: (AWP x 1.1) + \$4.00 dispensing fee *Medi-Cal Estimated Acquisition Cost (EAC): (0.83 * AWP) + \$7.25 dispensing fee

^{***}Selected cost reductions which are statistically significant between pre and post 2004 fee schedules for repackaged pharmaceuticals= p<0.05

Table III: Ordinary Least Square Regression of Log Total Average Cost Per NDC Using Dummy Variables

IIIa) Significant Predictor Variables of Repackaged Pharmaceuticals§

Manufacturer Packaged Pharmaceuticals (n=588 NDCs)										
	Ordinary Least Square (OLS) Regression of Total									
	Average Log Costs Per NDC									
		(Proc Reg in SAS)								
Variable	Parameter	Standard Error	t Value	Pr > t						
	Estimate									
Intercept	9.4121	0.64311	14.64	<.0001						
Brand with Generic*	-1.33483	0.59874	-2.23	0.0262						
Generic Medication**	-2.87503	0.44095	-6.52	<.0001						
Schedule II Narcotics	-0.94964	0.40617	-2.34	0.0197						
	Adjusted R-Square = 0.1157									

IIIb) Significant Predictor Variables of Manufacturer Packaged Pharmaceuticals§

Repackaged Pharmaceuticals (n=727 NDCs)								
	Ordinary Least Square (OLS) Regression of Total Average Log Costs Per NDC (Proc Reg in SAS)							
Variable	Parameter Estimate	Standard Error	t Value	Pr > t				
Intercept	6.06973	0.394	15.41	<.0001				
Brand with Generic*	-0.75622	0.3303	-2.29	0.0223				
Generic Medication**	0.6864	0.24548	2.8	0.0053				
Anti-Anxiety	-1.08606	0.43428	-2.5	0.0126				
Agents/Sleep Aids								
Time on Market < 7 yrs	0.91592	0.3338	2.74	0.0062				
	Adjusted R-Square = 0.092							

^{\$} All predictor variables selected in methods section were tested in the model, but only the variables listed above were all significantly predictive in the regression analysis (p<0.05)

^{*} Brand costs for drugs that have both brand and generic equivalents; ** Generic costs for drugs that have both brand and generic equivalents

Table IV: Cost Per Pill Comparisons for Manufacturer Packaged and Repackaged Pharmaceuticals

	Manufacturer Packageo	Repackaged Pharmaceuticals Total Average Costs Per			Total Pharmaceutical Total Average Costs Per Pill Per NDC						
	Costs Per Pill Per NDC			Pill Per NDC							
Pricing Options	Pre 2004 California	Post January	Post October	Pre 2004 California	Proposed	Proposed	Proposed	Pre 2004 California	Post January 2004	Post January 2004	Post October
	WC Rates:	2004 to Pre	2004 Estimated	WC Rates:	Rate:	Rate:	Rate:	WC Rates:	to Pre October 2004	to Pre October	2004 Estimated
	2002 CWCI Actual Costs	October 2004	Medi-Cal Rate:	2002 CWCI Actual	AWP-17%	AWP-10%	AWP-10%	2002 CWCI Actual	Rates:	2004 and Proposed	Medi-Cal Rate:
	Brand: 110%*AWP+	Rate:	AWP-17% +	Costs	+ \$7.25	+ \$7.25	+ \$8.75	Costs	Manufacturer:	Repack Rates:	AWP-17% +
	\$4.00	2002 Medi-Cal	\$7.25	Brand: 110%*AWP+				Brand: 110%*AWP	2002 Medi-Cal	Manufacturer:	\$7.25
	Generic: 140%*AWP+	Published	·	\$4.00				+ \$4.00	Published Costs§	2002 Medi-Cal	•
	\$7.00	Costs§		Generic: 140%*AWP				Generic: 140%*AWP	-	Published Costs§	
	Ψ7.00	Costa		+ \$7.00				+ \$7.00	2002 CWCI Actual	Repackaged:	
				ι ψ7.00				Ψ7.00	Costs	AWP-17% + \$7.25	
	Column #1	Column #2	Column #3	Column #4	Column #5	Column #6	Column #7	Column #8	Column #9	Column #10	Column #11
Grand Total	\$2.09	\$1.20	\$1.26	\$2.23	\$1.26	\$1.33	\$1.43	\$2.18	\$1.81	\$1.24	\$1.26
Total	¢2.75	¢1.70	¢1.70	d2.50	¢0.16	#O 04	¢2.40	¢2.10	DO 54	ф1 O1	¢1.06
Brand/Generic*	\$2.75	\$1.70	\$1.78	\$3.50	\$2.16	\$2.24	\$2.48	\$3.10	\$2.54	\$1.91	\$1.96
Alprazolam	\$2.27	\$1.05	\$1.42	No Use	No Use	No Use	No Use	\$2.27	\$1.05	\$1.05	\$1.42
Carisoprodol	\$5.54	\$4.66	\$3.74	\$5.61	\$3.67	\$3.90	\$4.09	\$5.57	\$4.98	\$4.33	\$3.71
Cyclobenzaprine	\$2.02	\$0.13	\$1.36	\$3.19	\$2.24	\$2.35	\$2.54	\$3.03	\$2.76	\$1.94	\$2.11
Fluoxetine	\$7.51	\$4.78	\$4.64	\$7.15	\$5.22	\$5.45	\$5.97	\$7.33	\$5.96	\$5.00	\$4.93
Hydrocodone	\$1.49	\$0.58	\$1.04	\$2.35	\$1.73	\$1.81	\$1.99	\$1.89	\$1.41	\$1.12	\$1.36
Morphine	\$3.54	\$2.28	\$2.13	No Use	No Use	No Use	No Use	\$3.54	\$2.28	\$2.28	\$2.13
Naproxen	\$2.24	\$1.09	\$0.79	\$5.34	\$3.09	\$3.13	\$3.66	\$4.47	\$4.15	\$2.53	\$2.44
Oxycodone	\$2.68	\$1.74	\$1.87	\$3.68	\$3.29	\$3.47	\$3.70	\$2.77	\$1.91	\$1.87	\$2.00
Propoxyphene	\$0.90	\$0.73	\$0.81	\$1.57	\$1.26	\$1.34	\$1.40	\$1.18	\$1.07	\$0.94	\$0.99
Relafen	\$2.36	\$2.36	\$0.77	\$2.66	\$0.90	\$0.94	\$1.02	\$2.63	\$2.63	\$1.03	\$0.89
Total Brand Only	\$4.30	\$2.84	\$1.26	\$3.66	\$1.13	\$1.19	\$1.28	\$3.85	\$3.42	\$1.64	\$1.13
Celecoxib	\$3.25	\$2.14	\$0.70	\$4.54	\$0.90	\$0.93	\$1.04	\$4.31	\$4.12	\$1.12	\$0.86
Gabapentin	No Use	No Use	No Use	\$1.88	\$1.27	\$1.36	\$1.39	\$1.88	\$1.88	\$1.27	\$1.27
Lansoprazole	\$6.68	\$4.14	\$0.44	\$1.66	\$1.16	\$1.23	\$1.29	\$5.97	\$3.79	\$3.71	\$0.54
Metaxalone	\$1.41	\$1.01	\$0.92	\$1.57	\$1.04	\$1.10	\$1.16	\$1.55	\$1.52	\$1.04	\$1.03
Omeprazole	\$7.38	\$5.02	\$0.44	\$6.97	\$0.80	\$0.82	\$0.95	\$7.23	\$5.72	\$3.52	\$0.57
Paroxetine	\$4.12	\$2.74	\$2.54	\$4.41	\$2.83	\$3.02	\$3.14	\$4.28	\$3.64	\$2.79	\$2.70
Rofecoxib	\$4.66	\$3.30	\$0.66	\$5.76	\$0.81	\$0.83	\$0.95	\$5.43	\$5.02	\$1.56	\$0.77
Sertaline	\$3.75	\$2.19	\$2.31	No Use	No Use	No Use	No Use	\$3.75	\$2.19	\$2.19	\$2.31
Tizaidine	\$2.27	\$1.39	\$1.41	No Use	No Use	No Use	No Use	\$2.27	\$1.39	\$1.39	\$1.41
Tramadol	\$1.40	\$0.91	\$0.90	\$2.07	\$1.41	\$1.49	\$1.59	\$2.00	\$1.96	\$1.36	\$1.36
Venlafaxine	\$2.99	\$1.90	\$1.84	\$2.82	\$1.77	\$1.90	\$1.96	\$2.93	\$2.22	\$1.86	\$1.82
Zolpidem	\$3.73	\$2.27	\$0.75	\$4.22	\$0.81	\$0.84	\$0.94	\$4.13	\$3.85	\$1.09	\$0.80
Total Generic*	\$1.26	\$0.57	\$1.05	\$1.36	\$1.08	\$1.15	\$1.21	\$1.32	\$1.04	\$0.88	\$1.07
Alprazolam	\$1.08	\$0.33	\$0.90	\$0.93	\$0.85	\$0.90	\$0.95	\$1.04	\$0.50	\$0.48	\$0.88
Carisoprodol	\$1.02	\$0.59	\$0.86	\$2.02	\$1.68	\$1.80	\$1.85	\$1.58	\$1.38	\$1.20	\$1.32
Cyclobenzaprine	\$2.09	\$1.48	\$1.78	\$1.35	\$1.27	\$1.34	\$1.43	\$1.54	\$1.38	\$1.32	\$1.40
Fluoxetine	\$3.45	\$1.15	\$2.68	\$3.26	\$2.62	\$2.83	\$2.86	\$3.42	\$1.53	\$1.42	\$2.67
Hydrocodone	\$0.67	\$0.30	\$0.61	\$1.01	\$0.93	\$0.99	\$1.04	\$0.91	\$0.79	\$0.74	\$0.83
Morphine	\$2.08	\$1.62	\$1.65	No Use	No Use	No Use	No Use	\$2.08	\$1.62	\$1.62	\$1.65
Naproxen	\$1.26	\$0.35	\$1.04	\$1.61	\$0.99	\$1.04	\$1.10	\$1.49	\$1.16	\$0.76	\$1.01
Oxycodone	\$0.59	\$0.36	\$0.53	No Use	No Use	No Use	No Use	\$0.59	\$0.36	\$0.36	\$0.53
Propoxyphene	\$0.57	\$0.23	\$0.57	\$0.82	\$0.82	\$0.87	\$0.92	\$0.79	\$0.76	\$0.77	\$0.80
Relafen	\$1.63	\$1.34	\$0.72	\$1.73	\$0.76	\$0.81	\$0.85	\$1.71	\$1.64	\$0.89	\$0.75

CWCI: California Workers' Compensation Institute; AWP: Average Wholesale Price; Medi-Cal: California Medicaid; WC: workers' compensation § 2002 Medi-Cal published rates obtained from Medi-Cal drug utilization files